UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff(s), v. INTUITIVE SURGICAL, INC., Defendant(s).	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **REBUTTAL EXPERT REPORT OF JEAN SARGENT** Complaint Filed: May 10, 2021

Highly Confidential – Subject to Protective Order

March 1, 2023

TABLE OF CONTENTS

I. INTRODUCTION

1. I am submitting this report at the request of Haley Guiliano LLP, as counsel for Surgical Instrument Service Company, Inc. ("SIS"), the named plaintiff in the lawsuit captioned on this report's first page. I am being compensated for my time spent in preparing this Report at an hourly rate of $500. If asked to testify in this lawsuit, I will be compensated at the hourly rate of $500 for deposition testimony and for testifying at trial. My compensation does not depend in any way on the outcome of this action.

2. On December 2, 2022, I submitted a report in this matter. My qualifications, including a summary of my career, a list of my professional publications and presentations, my curriculum vitae, and description of my current position are described in my Opening Report and in attachments to that report.[1]

3. Counsel for SIS has asked me to review and analyze the January 18, 2023, expert report submitted by Jason C. Goodwin on behalf of Intuitive Surgical, Inc.,[2] and provide any additional comments or opinions I have in a rebuttal report.

4. This rebuttal report is not intended to respond to every error, misstatement of fact, or misunderstanding of my Opening Report and the opinions stated in that report that appear in the Goodwin Report. Although I discuss certain issues raised by the Goodwin report, just because I don't respond to a particular assertion of fact, claim, or argument in the Goodwin Report does not mean that I agree with Mr. Goodwin on the issue.

5. Based on my review of the Goodwin Report, I note that the materials cited in the Goodwin Report are cumulative of materials that I already considered in preparing my Opening

[1] Expert Report of Jean Sargent, Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc., Case No. 3:21-cv-03496-VC, December 2, 2022 (the "Opening Report").
[2] Expert Report of Jason C. Goodwin, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, January 18, 2023 (the "Goodwin Report").

Report. Although I discuss certain issues below, I note that I stand by my Opening Report in its entirety, and that nothing stated in the Goodwin Report changes any aspect of the analysis of my Opening Report or the opinions I expressed in that report.

6. The materials that I considered in forming my opinions in this Rebuttal report are listed in Appendix A.

II. SUMMARY OF OPINIONS

7. In my experience, the Food and Drug Administration ("FDA") has the sole authority to decide when hospital-owned devices are subject to further regulation after their original purchase and use, not original equipment manufacturers ("OEMs") such as Intuitive.

8. When FDA has decided to assert authority over hospital-owned instruments and devices after their original purchase and use, it has engaged in extensive informational and educational campaigns to provide notice and clear standards to hospitals and industry participants such as independent service organizations ("ISOs"). Only after such industry outreach is completed does FDA engage in enforcement of those regulations.

9. An example of such a campaign was the introduction of FDA regulation for reprocessing of single use devices ("SUDs"). Although OEMs have regularly sought for FDA to assert similar authority over multi-use instruments and devices such as Intuitive's EndoWrists, despite my years of experience in hospital systems and industry organizations, I am not aware of FDA ever engaging in a similar informational or educational campaign for multi-use instruments and devices, let alone ever bringing an enforcement action against a hospital or ISO for engaging in activities – however those activities might be classified as reprocessing, refurbishing, repair, service, or remanufacturing – with such multi-use instruments and devices.

III. DISCUSSION

10. Mr. Goodwin's opinion cites to a number of Intuitive documents regarding the number of uses for EndoWrist instruments.[3] As Mr. Goodwin's selective excerpts admit, some of these documents merely inform users of Intuitive's "license"[4] or are tables that state "Number of Uses / Activations",[5] while others generally describe Intuitive's use counter in the manual for the system, not the EndoWrist instruments.[6] What these documents convey to hospital staff is that there is a license imposed by Intuitive, not any sort of FDA-imposed, regulatory limitations on the number of uses for EndoWrists or a hospital's ability to directly perform any activity to further use the EndoWrists beyond the limitations on number of uses Intuitive imposes on purchasers.

11. OEMs have long sought to limit the activities of hospitals and third parties such as ISOs that work with hospitals to reuse, repair, or otherwise work with OEM multi-use instruments and devices. As I explained in my opening report, hospitals have long done so despite the protests of OEMs, resulting in substantial cost savings and without sacrificing patient safety. Absent actual intervention by the FDA, or some other leverage, an OEM's unilateral assertions are no reason for a hospital to stop engaging in such long-standing and legitimate activities with respect to FDA-cleared devices that the hospitals have already purchased from the OEM.

12. For example, hospitals (directly, or through ISOs) reprocessed, reused, and repaired instruments and devices that OEMs labeled as "single use" for years. For example, throughout the 1990s hospital systems that I worked at reused a variety of devices that were labeled as "single use" by OEMs, such as expired products including IV tubing, catheters, and blades. The key consideration for hospitals, as always, was whether we believed such reuse could be

[3] Goodwin Report at ¶¶ 16-22.
[4] *E.g.*, Intuitive-00000501-639 at Intuitive-00000511-512.
[5] *E.g.*, Intuitive-01232035-080.
[6] *E.g.*, Intuitive-00096563-864 at Intuitive-00096691-692.

performed while maintaining standards of patient care and safety, such as through proper reprocessing, repair, or servicing.

13. Throughout this time there was substantial discussion within the industry about FDA potentially regulating this reuse of SUDs. As I understand Intuitive is attempting to do here, OEMs attempted for years to convince FDA to regulate reuse of SUDs. During this time, and prior to FDA taking any definitive action, hospitals continued their preexisting practices.

14. By the late 1990s to early 2000s, FDA decided to regulate reuse of SUDs. In addition to promulgating official regulations and standards, FDA embarked on a substantial educational campaign to both hospitals and ISOs to help them understand the SUD regulations and their scope prior to FDA engaging in any enforcement actions.

15. In 1999, I was approached by the FDA to assist with dissemination of information regarding the guidance that indicated all single use items that are being re-sterilized must have the process validated by an outside organization. I provided education to local and national conferences to bring attention to the fact that hospitals (and vendors working on the hospitals' behalf) could no longer sterilize products without validation by FDA. In addition, if a hospital chose to continue to sterilize single use devices, they would need to register with the FDA as a manufacturer and follow good manufacturing processes.

16. This informational and education process took approximately eighteen months before FDA began to formally enforce its SUD regulations. This process is consistent with my experience with FDA. There are many "gray areas" in FDA regulations and FDA largely stays out of the operations of hospitals and their service providers such as ISOs, as opposed to OEMs which I understand to be FDA's primary concern and jurisdiction. The FDA has limited authority over hospitals and their efforts to regulate SUDs were an exception to prior generally accepted practices. From a hospital's perspective, FDA largely works through what it actually enforces,

and provides hospitals with ample notice and information before imposing new and costly policies on hospitals and their service providers.

17. In my decades of work in major hospital systems and numerous hospital administration and management associations, I'm not aware of FDA taking any enforcement action against a hospital or a hospital-employed ISO for reusing multi-use instruments or devices despite OEM use restrictions and whether those actions might be categorized as repair, service, reprocessing, refurbishment, or remanufacturing. Nor am I aware of FDA engaging in any outreach or educational activities to hospitals indicating that FDA had definitive standards governing such re-use of multi-use devices or instruments by hospitals or their service providers, let alone indicating an intent to engage in future enforcement against these activities.

18. Based on my experience, including with FDA's regulation of SUDs, hospital systems would understand FDA's inaction towards hospitals on reuse of multi-use instruments or devices despite OEM use restrictions as an indication that FDA has not yet created definitive guidance on these activities and does not presently intend to engage in enforcement actions regarding such activities. Absent other leverage from an OEM to prevent such reuse, it would be appropriate for hospitals to engage in such reuse in accordance with approved processes and their best judgment on cost savings and best practices for patient care.

19. In my decades of work in major hospital systems and numerous hospital administration and management associations, I'm not aware of FDA taking any enforcement action against a hospital or a hospital-employed ISO for actions taken to use Intuitive's EndoWrist instruments beyond the use limits of the Intuitive "license," whether or not such reuse might be categorized as repair, service, reprocessing, refurbishment, or remanufacturing, or involve resetting the Intuitive use counter. Nor am I aware of FDA engaging in any outreach or educational activities to hospitals indicating that FDA had definitive standards regarding use of

Intuitive's EndoWrist instruments beyond the use limits of the Intuitive "license," including reset of the use counter, let alone indicating an intent to engage in future enforcement activities for these activities.

20. Based on my experience, including with FDA's regulation of SUDs, hospital systems would understand FDA's inaction towards hospitals on the use of Intuitive's EndoWrist instruments beyond the use limits of the Intuitive "license" as an indication that FDA has not yet created definitive guidance on these activities and does not presently intend to engage in enforcement actions regarding such activities. Absent other leverage from Intuitive such as rendering da Vinci robots inoperable, hospitals would feel free to engage in such continued use of EndoWrist instruments in accordance with their best judgment on cost savings and patient care.

Jean Sargent

March 1, 2023

Materials Considered

- Expert Report of Dr. Maxwell V. Meng (Jan. 18, 2023) (*Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC)
- Expert Report of Christy Foreman (Jan. 18, 2023) (*Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC)
- Deposition of Mark Early (Oct. 6, 2022)
- Deposition of Dr. Michael Burke (Sept. 27, 2022)
- 30(b)(6) Deposition of Richard Teal (Nov. 18, 2022)
- Deposition of Dr. Greta Bernier (Nov. 7, 2022)
- Deposition of Dr. Ricardo Estape (Oct. 22, 2022)
- Deposition of John Wagner (Oct. 11, 2022)
- Deposition of Dipen Maun (Nov. 8, 2022)
- Deposition of Clifton Parker (May 4, 2021)
- Deposition of Keith Johnson (October 27, 2022)
- 30(b)(6) Deposition of Keith Johnson (October 27, 2022)
- ASS'N OF PERIOPERATIVE REGISTERED NURSES (AORN), *Guideline for Medical Device and Product Evaluation, in* GUIDELINES FOR PERIOPERATIVE PRACTICE (2022)
- da Vinci S and Si Reprocessing Instructions Appendices, PN 552268-03 Rev. B (2021)
- CTR. For DEVICES & RADIOLOGICAL HEALTH, FDA, Labeling: Regulatory Requirements for Medical Devices, 15-17 (Aug. 1989), https://www.fda.gov/media/74034/download (section titled Labeling for Investigational and 510(k) Devices)
- FDA, Reprocessing Medical Devices in Heath Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff (2015), https://www.fda.gov/media/80265/download
- Device Labeling, FDA (Oct. 23, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling
- Manufacturers Instructions for Use - Expectations Regarding Access To IFUs for Medical Instruments and Devices, JOINT COMM'N (Oct. 21, 2021), https://www.jointcommission.org/standards/standard-faqs/ambulatory/infection-prevention-and-control-ic/000002250/
- da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, PN 554324-01 Rev. B
- Discussion with Keith Johnson, Executive Vice President, Sales and Clinical Programs at SIS
- Intuitive-00039624-651
- Intuitive-00512620-739
- Intuitive-02047253-232
- Intuitive-02046437-478
- Intuitive-00000501-639
- Intuitive-00002201-501

- Intuitive-00096563-964
- Intuitive-00279588-888
- Intuitive-00284844-945
- Intuitive-00654768
- Intuitive-00670595-716
- Intuitive-00676719-840
- Intuitive-01163789-890
- SIS000202-04
- SIS045231-32
- SIS047433-35
- SIS106493-98
- SIS107399-442
- SIS117733-49
- SIS346267
- SIS357819-23
- SIS357824-37